UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,206	02/09/2001	Michael Fritz	RDID0028US	5556

20306 7590 06/26/2003

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,206	FRITZ ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-68* is/are pending in the application.

4a) Of the above claim(s) *42-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 15) filed on April 15, 2003 has been entered.

2. Claims 36-41 and 68 are considered for examination. Non-elected claims 42-67 are withdrawn from further consideration as stated in the previous office actions.

Response to Arguments

3. Applicants' response to office action (Paper No. 15) is fully considered and found not persuasive because of the reasons set forth below.

The following is the rejection made in the previous office action under 35 USC 102(e):

Claims 36-41, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Furcht et al. (USPN. 6,054, 277).

Furcht et al. teach a device or apparatus or detecting nucleic acids in a sample comprising (a) a binding space (silicon substrate or collection pads) for immobilizing the nucleic acids and separating impurities (see column 4, lines 15-35, column8, lines 30-50); (b) an amplification space (thermocycling and amplification chamber) for amplifying comprising at least part of the binding space (see column 4, lines 15-67, and column 6, lines 51-61, column 8, lines 30-50); and a detection space for detecting the nucleic acids (see column 4, lines 22- 35). Furcht et al. also disclose that the apparatus further comprises (I) reagents for purification and amplification and detection of the nucleic acid (see column 8, lines 30-67, column 9, lines 1-16); (ii) capillary space connecting amplification space, binding and detection space (see column 4, lines 51-57, column6, lines 33-61); (iii) capillary reaction vessel surrounded by heatable element comprises epoxy-like material (metal layer) deposited on to silicon wafer (see column 10, lines 28-47,

column 6, lines 33-46); and (iv) capillary space comprises silicon (glass) wafers (see column 10, lines 28-33). Thus, the disclosure of Frucht et al. meets the limitations in the instant claims.

Response to arguments:

Applicants' amendment and arguments are fully considered and found not persuasive. Applicants' argue that claim 36 has been amended to reflect the device as integrated device and referred to the instant specification to indicate that the detection of nucleic acids is accompanied in this closed device such that binding as well as amplification of nucleic acids are carried out in the same space. This argument is fully considered however, examiner notes that specification can not be read in to the claims, hence the limitation that "binding as well as amplification are carried out in the ***same*** space" is **not** in the instant claim 36.The device as taught by Furcht et al. comprises an integrated device as recited in the instant amended claim 36. Further the instant claim recites three spaces in the integrated device, which is disclosed by Furcht et al.

With reference to the claim 68, Applicants argue that heatable metal layer coated on the reaction vessel disclosed by Furcht et al. comprise two opposed, spaced apart microchip heaters and the opposed microchips of Furcht et al. are not a capillary reaction vessel surrounded by heatable metal layer as recited in the instant claim 68. This argument is fully considered and found not persuasive because the instant claim 68 does not recite hetable metal layer as a continuous layer around the capillary reaction vessel. Further the claim is in open "comprising" format wherein any additional element could be included and meets the limitations as taught by Furcht et al. Therefore the rejection is maintained.

New Grounds of Rejections necessitated by amendment

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-41, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al. (USPN. 6,379,929).

Burns et al. teach an apparatus for detecting nucleic acids in a sample comprising (a) a binding space (substrate) for purifying and immobilizing the nucleic acids and separating impurities (see column 3, lines 66-67, column 4, lines 1-4, lines 22-39); (b) an amplification space (reaction chamber) comprising at least part of the binding space (substrate) for amplifying nucleic acids (see column 5, lines 58-64, column 4, lines, lines 1-4, lines 49-67, column 5, lines 1-3); (c) a detection space for detecting the nucleic acids (see column 8, lines 66-67, column 9, lines 1-12, lines 34-44, column 10, lines 50-57). Burns et al also teach that (i) the device or system could be coupled into integrated format (see column 11, lines 8-13); (ii) the reaction vessel is surrounded by a heatable metal layer (column 6, lines 7-17, lines 46-65); (iii) the microfabricated binding space comprises a part of at least amplification space and at least a detection space (see column 8, lines 66-67, column 9, lines 1-12, column 11, lines 37-51) (iv) the binding space and amplification space comprises a capillary space (channel) made up of glass (see column 5, lines 15-64) (v) the device comprises multiple parallel units of single silicon wafer to processes a large number of isothermal amplification reactions (see column 11, lines 14-

20); (vi) the device comprises reagents for processing nucleic acids (see column 10, lines 6-16). Thus the disclosure of Burns et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
June 18, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER